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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,317	07/17/2003	Brian R. Micheli	DI-5829	3439

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EXAMINER	
DRODGE, JOSEPH W	
ART UNIT	**PAPER NUMBER**
1723	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/623,317	MICHELI, BRIAN R.	
	Examiner	Art Unit	
	Joseph W. Drodge	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-17 and 32-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-17 and 32-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 9-17,32-44 and 55-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Specification as originally filed does not support the language in claim 9 as amended "reservoir coupled fluidly to the cycler" in claim 9 or "container fluidly with a circulator of the dialysate (therapy fluid)" as now recited in claims 32,38 and 55. Such recitations thus constitute ***NEW MATTER***.

It is acknowledged that Figure 3 and page 20, lines 3-21 do support the claiming of the reservoir or container "branching off of the closed loop" as now also claimed and would support recitation of one or more pumps arranged to pump into and out of such reservoir or container. Page 20, lines 20-21 suggest such pump(s) as coupled to the system or fluid circuit "via a cycler"; however it is unclear if this is the same cycler described on pages 16-17 of the Specification that circulates dialysate along the closed fluid path of the circuit.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9-12,15-17,32-41,43-49, and 52-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al Journal Publication "Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration" from Scholarly Review, ASAIO Journal 1999, pages 372-378 in view of Devries patent 3,545,438 (of record with a previously submitted IDS statement).

Roberts et al disclose the claimed peritoneal dialysis system including elements of dual lumen catheter (page 372, 1st column, and components shown in figure 3 that include closed loop fluid circuit, plural dialysate supplies, therapy fluid/osmotic agent or 'infusate' supply, cycler pumps, cleaning device at least including a sorbent cartridge and a discharge path/drain in the vicinity of the dialysate supplies. Also shown in figure

3 is a surge reservoir, in the closed loop fluid circuit. For independent claims 28,and 51, removal of urea is discussed on page 373, 1st column and in Table 1.

Regarding various dependent claims; two separate dialysate supplies totaling less than 4 or 6 liters are shown as well in figure 3, with osmotic agent supply inherently totaling less than 1.5 liters (see discussion on page 373, 2nd column, removal of urea by either non-selective sorbent or urease-urea removal specific media (page 374, 2nd column and page 376, 2nd column), presence of sorbent material (page 373, 2nd column), maintaining of high urea and creatinine clearance levels (see Table 1 on page 376), the infusate constituting electrolytes and components with osmotic diffusive enhancing characteristics (page 376, see paragraph entitled "Wearable Regeneration Systems"), treatment periods of 8 hours or less (page 376, 2nd column, 3rd paragraph), continuous circulation and supply portions of 4 liters or less each (page 372, 1st column), and option of lower 3 liter or less amounts of osmotic solution utilized (see especially page 374 concerning treatment of relatively smaller canine systems). For claim 35,38 and 45 and claims dependent therefrom ultrafiltration is discussed under Section Header "Wearable Regeneration Systems".

The pending claims 9-17,32-44 and 55-60 all differ from Roberts in requiring a reservoir (or the reservoir) as branching off of the closed loop, fluidly coupled to the closed loop and cycler and adapted to provide a variable increase in volume capacity so as to compensate for increase in fluid volume in the circuit during treatment, such as by addition of fresh dialysate. DeVries teaches a closed loop peritoneal dialysis circuit having a supplemental branched off container, tank or reservoir 44 that is fluidly coupled to surge circulation tank 16 and also to cycler 64 via various conduits and via valves 42 and 30. The supplemental tank allows for increased capacity for holding of overflow and excess fresh dialysate solution that enters the closed loop from fresh dialysate source 10 (column 4, lines 12-43 and figures) and can be selectively drained (column 4, lines 35-42) and used to measure the amount of dialysis solution in circulation after a treatment cycle to deterimine the efficacy of the treatment (column 4, line 43-column 5, line 5). It would have been obvious to one of ordinary skill in the dialysis art, at the time of the invention, to have supplemented the Roberts system, with the branched container or reservoir of DeVries, in order to safely allow introduction of substantial volumes of fresh dialysate into the circuit, and to measure amounts of dialysate in circulation.

Claims 45-54 differ from Roberts in requiring the draining of the fluid circuit be at an effective rate to compensate for the increase in fluid volume (such as provided by a supplemental branched reservoir). DeVries also teaches such draining (column 4, lines 35-42). Again, it would have been obvious to one of ordinary skill in the art to have institued such supplemental fluid storage and drainage, as taught by DeVries to safely allow introduction of substantial volumes of fresh dialysate into the circuit.

Claims 13,14,42,50,51 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Roberts et al Journal Article in view of DeVries patent 3,545,438 as applied to claims 9,38,45 and 55 and further in view of Shockley et al patent 5,631,025.

Claims 13,14,42,50,51 and 60 further differ in requiring that the osmotic agent fluid supply include dextrose. Shockley et al teach use of dextrose at column 5, lines 18-25 and supporting rationale. It would have been obvious to one of ordinary skill in the art to have included dextrose in the infusate supply of Roberts et al, as taught by Shockley, in order to enhance removal of various toxins by ultrafiltration from the recirculating dialysate.

Applicant's arguments with respect to claims 9-17 and 32-60 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can reached at 571-272-1151. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

June 24, 2006

JOSEPH DRODGE
PRIMARY EXAMINER